

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

C.A. No. 21-1015 (JLH)

PUBLIC VERSION

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**SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN
AUSTRALIA'S REPLY BRIEF IN SUPPORT OF THEIR MOTIONS TO EXCLUDE
CERTAIN OPINIONS AND TESTIMONY OF
PLAINTIFF/COUNTER-DEFENDANTS' EXPERTS**

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TABLE OF ABBREVIATIONS

Abbreviation	Description
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'361 Patent	U.S. Patent No. 9,708,361
'092 Patent	U.S. Patent No. 10,385,092
'461 Patent	U.S. Patent No. 10,407,461
'106 Patent	U.S. Patent No. 10,487,106
'741 Patent	U.S. Patent No. 10,647,741
'217 Patent	U.S. Patent No. 10,662,217
'322 Patent	U.S. Patent No. 10,683,322
ASO	Antisense oligonucleotide
<i>Bold and Italic</i>	Emphasis added unless indicated otherwise
DMD	Duchenne muscular dystrophy
Ex. ____	Exhibit ____ ¹
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Patents	U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; 10,683,322
PMO	Phosphorodiamidate morpholino oligomer
POSA	Person of ordinary skill in the art
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
UWA	Counter-Plaintiff The University of Western Australia
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827

¹ Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Replies to Their Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Plaintiff/Counter-Defendants' Experts.

I. INTRODUCTION

For the reasons discussed in their opening brief (D.I. 395) and below, Sarepta and UWA respectfully request that the Court exclude:

- (1) the opinions and testimony of Scott E. Kamholz, Esq. relating to inequitable conduct;
- (2) the opinions and testimony of Dr. Christine C. Esau relating to noninfringement of the Wilton Patents;
- (3) the opinions and testimony of Dr. Christine C. Esau and Dr. Michelle L. Hastings relating to willful infringement and the opinions and testimony of Dr. Matthew J. A. Wood relating to conception (collectively, the “state of mind” opinions and testimony); and
- (4) the opinions and testimony of Dr. Nathan W. Luedtke relating to infringement of the ’322 Patent under the doctrine of equivalents.

II. *REPLY IN SUPPORT OF MOTION #1: EXCLUSION OF DR. KAMHOLZ’S OPINIONS AND TESTIMONY*

A. NS’s Interpretation of Dr. Kamholz’s “Knew or Should Have Known” Opinion Confirms That the Opinion Should Be Excluded

NS does not dispute that the “knew or should have known” standard is incorrect under *Therasense*. See generally D.I. 456. NS also admits that Dr. Kamholz applied this incorrect standard in rendering his inequitable conduction opinions. See D.I. 456 at 3 (NS admitting that Dr. Kamholz opined that the individuals involved “knew or should have known the declarations contained false or misleading statements”). Because NS concedes that Dr. Kamholz relies on an incorrect legal standard, his testimony should be excluded. See *Sprint Commc’ns Co. L.P. v. Cox Commc’ns Inc.*, 302 F. Supp. 3d 597, 619 (D. Del. 2017) (excluding expert testimony under Daubert that is “contrary to the law and [], therefore, unhelpful and likely to confuse a jury”).

NS doubles down on its reliance on the incorrect “knew or should have known” standard by arguing that Dr. Kamholz did not “take a position on which of those is the case.” D.I. 456 at 3.

[REDACTED]

NS argues that the Court should render the “ultimate opinion as to whether Wilton, Fletcher or Mandragouras knew” certain information. *Id.* But this is why Dr. Kamholz’s opinions are unhelpful to the Court and should be excluded. The Court does not need to be educated by Dr. Kamholz as to the legal standard, let alone the wrong one. *Patrick v. Moorman*, 536 F. App’x 255, 258 (3d Cir. 2013) (FED. R. EVID. 704 “prohibits experts from opining . . . about the law or legal standards”). Beyond that, Dr. Kamholz concedes he is not opining that the facts support either of the “knew” or (legally wrong) “should have known” conclusions. D.I. 425-1 (Ex. 33), 48:11-50:14. His inappropriate, legally deficient opinions should be excluded.

B. Dr. Kamholz’s Disclaimers Cannot Save Inadmissible Technical and State of Mind Opinions

NS argues that “Dr. Kamholz has expressly disclaimed offering technical opinions.” D.I. 456 at 2-3. But his purported disclaimer is irrelevant because his actual opinions squarely address technical issues. *See, e.g.*, D.I. 425-1 (Ex. 24), ¶34 (“[REDACTED]

[REDACTED]”); *see also id.*, ¶¶51-56, 58, 60-74, 76-78, 83; *id.* (Ex. 25), ¶¶21, 23, 32.

[REDACTED] *See* D.I. 456 at 1-2 ([REDACTED]

[REDACTED]). There is no dispute that Dr. Kamholz lacks the technical background to opine on these highly technical issues. He is also unqualified to opine on how these scientific facts relate to “a rejection under 35 U.S.C. § 112” (*id.*), which must be assessed from “the perspective of a person of ordinary skill in the art.” *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2011) (en banc). Dr. Kamholz’s opinions plainly

[REDACTED]

show that he proffers technical testimony purporting to weigh and analyze the sufficiency of the scientific evidence that the inventors possessed at the time of their declaration. By his own admission, Dr. Kamholz lacks adequate technical training to offer such opinions, and his unqualified opinions should therefore be excluded.

NS's argument that Dr. Kamholz is not opining on "state of mind" is similarly inconsistent with Dr. Kamholz's erroneous "knew or should have known" standard. NS argues that he is "not offer[ing] opinions as to [REDACTED]" of certain information. D.I. 456 at 3. Yet, at the same time, NS admits that Dr. Kamholz is opining that these individuals "knew or should have known." *Id.* That is quintessentially improper state of mind testimony. Courts routinely exclude such testimony as improper. D.I. 395 at 3, 5 (collecting cases).

C. Dr. Kamholz's Opinions Are Not Helpful to the Factfinder

While NS claims that Dr. Kamholz's opinions are "helpful to the factfinder" (D.I. 456 at 1-2), his opinions are anything but. As illustrated above, Dr. Kamholz's application of the incorrect "knew or should have known" standard exemplifies how his opinions would cause confusion. His unscientific opinions on technical evidence and his guesswork on the state of mind of the inventors and Ms. Mandragouras also have no value to the factfinder. Similar defects infect his inequitable conduct opinions concerning the NS Patents, as he proffers improper technical testimony despite his lack of qualifications and speculates as to what the Examiner would have done had certain technical information been disclosed during prosecution. D.I. 395 at 7 n.3. Dr. Kamholz's opinions fail to meet the threshold standard of FED. R. EVID. 702 and should be excluded.

III. REPLY IN SUPPORT OF MOTION #2: EXCLUSION OF DR. ESAU'S NON-INFRINGEMENT OPINION AND TESTIMONY

As explained in Sarepta's Motion for Summary Judgment of Infringement (D.I. 409) and related papers, NS's expert Dr. Esau applied a claim construction precluded by the Court's

Markman ruling as the basis for her non-infringement opinion. NS admits that her construction is nonsensical as it would not cover any ASOs. *See* D.I. 460 at 8; D.I. 466, 1.23. NS also admits that NS's validity expert Dr. Hastings applied a contrary construction. D.I. 457 at 1.

NS completely ignores the caselaw cited by Sarepta (D.I. 409 at 9) that excluded expert testimony contrary to claim construction. *See, e.g., CAO Lighting, Inc. v. Gen Elec. Co.*, C.A. No. 20-681-GBW, 2023 WL 1930354, at *4-7 (D. Del. Jan. 30, 2023) (excluding expert opinion contrary to claim construction); *Minerva Surgical, Inc. v. Hologic, Inc.*, C.A. No. 18-217-JFB-SRF, 2021 WL 3048447, at *8-9 (D. Del. July 20, 2021) (striking technical expert's infringement testimony because the expert applied a claim construction that the court had rejected).

The only case cited by NS, *Intel Corp. v. Future Link Sys., LLC*, 268 F. Supp. 3d 605, 614 (D. Del. 2017) is irrelevant, because it does not address a situation like the present one where an expert's opinion is contrary to the Court's *Markman* ruling. For the reasons set forth herein, in Sarepta's opening brief (D.I. 395), and in the papers related to Sarepta's Motion for Summary Judgment of Infringement (D.I. 409), Dr. Esau's non-infringement opinion should be excluded in its entirety.

IV. REPLY IN SUPPORT OF MOTION #3: EXCLUSION OF THE "STATE OF MIND" OPINIONS AND TESTIMONY OF NS'S EXPERTS

A. The "Willfulness" Opinions from NS's Experts Improperly Speculate as to Sarepta's State of Mind, Lack Technical Value, and Are Incomplete

NS's sole argument defending the state of mind opinions of Drs. Esau and Hastings is that they address underlying technical facts. *See* D.I. 458 at 1-3. But the opinions in question plainly speculate as to state of mind, are not based on any technical issues that require expert testimony, and are based on an incomplete consideration of the record.

As an initial matter, Drs. Esau and Hastings offer improper "state of mind" opinions that extend well beyond the evidence, which is clear from the words of the experts themselves. *E.g.*,

[REDACTED]

D.I. 422-1 (Ex. 20), ¶214 (Dr. Esau: Sarepta “knowingly, willfully, and deliberately” infringed); D.I. 425-1 (Ex. 23), ¶¶84-85 (Dr. Hastings: Sarepta “cannot have had a reasonable, good faith belief”); *see* D.I. 395 at 11-12. “[I]t is not helpful to jurors for an expert to tell them what he thinks about an institution’s intent.” *Trading Techs. Int’l, Inc. v. IBG LLC*, Case No. 10 C 715, 2020 WL 12333010, at *2 (N.D. Ill. Oct. 21, 2020).

Further, the purported facts underlying their improper testimony are **not technical**, and therefore do not require technical expert testimony. Dr. Esau states that Sarepta [REDACTED]

[REDACTED]—none of which require explanation from a technical expert.² *See* D.I. 422-1 (Ex. 20), ¶¶206-14, 334-42. Dr. Hastings speculates about Sarepta’s “belief,” but fails to cite **any evidence** as to Sarepta’s state of mind other than her subjective belief regarding the validity of the NS Patents. *See* D.I. 425-1 (Ex. 23), ¶¶84-85. These opinions are not “technical.”

Drs. Esau and Hastings also both conspicuously fail to address the most probative evidence of Sarepta’s belief, [REDACTED]

[REDACTED] *See* Ex. 9; Ex. 10; D.I. 39-4. The willful infringement testimony of Drs. Esau and Hastings, which speculates as to Sarepta’s state of mind based on incomplete evidence, should be excluded.

² In a footnote, NS improperly contends for the first time that Dr. Dowdy “should be precluded from offering **any** testimony regarding Sarepta’s improperly filed IPRs,” even though its experts opined on those IPRs. D.I. 458 at 2 n.1; D.I. 422-1 (Ex. 20), ¶¶211, 312. NS did **not** seek to exclude Dr. Dowdy’s willfulness opinion based on Sarepta’s IPRs—its *Daubert* motion was limited to obviousness. *See* D.I. 419, ¶4; *see also EIS, Inc. v. WOW Tech. Int’l*, Case No. 1:21-cv-01015-GBW, Pretrial Conference Tr., at 5:19-6:7 (D. Del. Sept. 5, 2023) (Ex. 12) (denying motion to exclude IPR evidence for “willfulness claims”).

B. Dr. Wood's Improper and Deficient "Conception" Opinions Should Be Excluded

The Court should exclude Dr. Wood's improper opinions because they do not properly address issues relevant to conception, do not take into account any evidence of conception beyond publicly available information, and delve into questions of patent validity (rather than conception) that Dr. Wood swore he would not opine on.

First, although it is undisputed that the pertinent portion of Dr. Wood's opening expert report does not mention the term "POSA" at all, NS nevertheless argues his opinions are permissible as they were allegedly based on the "perspective of a POSA." D.I. 458 at 3-4. NS is wrong. Testimony from the perspective of a POSA is irrelevant to conception. Conception is the "formation in the *mind of the inventor*, of a definite and permanent idea of the complete and operative invention." *Burroughs Wellcome Co. v. Barr Lab'ys, Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994). To the extent Dr. Wood speculates directly about the inventors' state of mind (as in his opening report), he is offering improper state of mind testimony. *See id.* To the extent his testimony speculates about what a POSA would have understood about the inventors' state of mind (as in his reply report), this is irrelevant to conception.³ *See Robocast, Inc. v. Microsoft Corp.*, No. 10-1055-RGA, 2014 WL 202571, at *1 (D. Del. Jan. 16, 2014) ("Conception is a mental process, which is ordinarily proved via inventor testimony.").

Second, his testimony is not based on sufficient facts. Dr. Wood did not consider the testimony of the inventors or the contemporaneous record from Dr. Wilton's laboratory. *See* D.I. 425-1 (Ex. 29), ¶2. All that Dr. Wood offers is his subjective review of the Wilton Patents and

³ Conception is complete when "only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Burroughs Wellcome*, 40 F.3d at 1228. But Dr. Wood does not evaluate the amount of experimentation needed to reduce the invention to practice. Instead, he speculates about what a POSA would have understood the inventors of the Wilton Patents to have believed they invented. D.I. 458 at 3-4. This is not relevant to conception.

his speculation as to the state of mind of the inventors. That is not a proper evaluation of conception, and his testimony is deficient under FED. R. EVID. 702.

Third, Dr. Wood's testimony wrongly intermingles two separate legal concepts, "conception" (an idea in the mind of the inventors) and "written description" (whether a POSA would have believed that "the inventor actually invented the invention claimed"). *See Ariad*, 598 F.3d at 1351. Dr. Wood's blurring of these concepts is particularly problematic [REDACTED] [REDACTED] and his sworn declaration before this Court [REDACTED]. *See* D.I. 298; D.I. 307; D.I. 385; D.I. 309, ¶3. Dr. Wood's improper testimony should be excluded.

V. REPLY IN SUPPORT OF MOTION #4: EXCLUSION OF DR. LUEDTKE'S DOCTRINE OF EQUIVALENTS OPINIONS AND TESTIMONY

NS has not met its burden to show that Dr. Luedtke's testimony is helpful, is based on sufficient facts and data, and reflects reliable application of reliable principles and methods to the facts of this case. *See* FED. R. EVID. 702. First, NS [REDACTED]

[REDACTED] D.I. 459 at 2-3. In the paragraphs NS cites, Dr. Luedtke mentions only [REDACTED] *Id.* (citing D.I. 468 (Ex. 52) ¶¶184, 187; *id.* (Ex. 53), n.1). [REDACTED]

[REDACTED] Instead, Dr. Luedtke opines [REDACTED] [REDACTED] D.I. 395 at 16, 17-18. This failure violates the All Elements Rule. *Id.* at 15-18.

Second, Dr. Luedtke's opinions apply incorrect legal standards, as Sarepta explained. D.I. 395 at 14-20. NS does not provide *any legal authority* to dispute these legal standards, such as how it is legally wrong to use a hypothetical claim to evaluate whether an accused process meets claim limitations under the doctrine of equivalents. *See* D.I. 459 at 2-3. In fact, NS's opposition

does not cite a single case. See D.I. 459. NS cites only Dr. Luedtke to argue that “a hypothetical claim analysis is necessary where, as here, the alleged infringer has raised” an ensnarement defense. *Id.* at 2. But Dr. Luedtke **did not use** his hypothetical claims to respond to Sarepta’s ensnarement challenge. Instead, [REDACTED]

[REDACTED] D.I. 468 (Ex. 52), ¶¶ 193-95. Moreover, Dr. Luedtke “is not a legal expert” and does “not offer legal opinions.” *Id.*, ¶17; see also Ex. 1, 37:10-17, 91:25-92:6. His opinions should be excluded.

VI. CONCLUSION

For the forgoing reasons, Sarepta and UWA respectfully request that the Court exclude opinions and testimony of NS’s experts discussed herein and in their opening brief (D.I. 395) and specified in the previously filed motions (D.I. 391-394).

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CERTIFICATE OF SERVICE

I hereby certify that on January 26, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 26, 2024, upon the following in the manner indicated:

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